



BRS Stakeholder Update



Spring 2007

Message from the Acting Deputy Administrator

Greetings! I am pleased to provide you, our valued stakeholders, with an update on what has been keeping APHIS' Biotechnology Regulatory Services (BRS) program busy over the past several months. First, I'd like to congratulate our former Deputy Administrator, Cindy Smith, who was recently named Associate Administrator of APHIS. Cindy has contributed greatly to the growth and evolution of BRS and we wish her well in all of her future endeavors with the agency. During this time of transition, I am honored to serve as the acting BRS Deputy Administrator. This program is faced with so many diverse and constantly changing issues, and I am grateful to work with some of the most dynamic, dedicated, and hard working professionals in all of government.

We hope you find this stakeholder update informative, and encourage you to visit our Web site (<http://www.aphis.usda.gov/biotechnology>) for the latest news and information. If you have not previously registered with our on-line BRS stakeholder registry, please go to <https://web01.aphis.usda.gov/BRS/BRSWeb.nsf> and sign up to ensure that you receive all future stakeholder updates.

Sincerely,

Rebecca Bech
BRS Acting Deputy Administrator

APHIS Clarifies Policy on Low Level Presence

On March 27, 2007, BRS clarified its existing approach for handling situations in which regulated genetically engineered (GE) plant material becomes mixed at low levels with commercial seeds and grain. This policy is not new, but rather a description of how BRS currently evaluates and responds to these incidents. In light of continuing international discussions regarding low-level presence (LLP) of regulated GE plant material, APHIS is taking this opportunity to formally state our approach.

Developers must comply with all APHIS regulations and permit conditions to prevent the release of regulated GE material. However, when LLP incidents occur, the agency's policy is to respond with actions appropriate to the level of risk, determined by a scientific assessment and warranted by the facts in each case. APHIS will initiate an inquiry whenever regulated material is mixed with commercial seeds or grain to evaluate any risk, to determine the circumstances surrounding the release and to determine whether remedial and/or enforcement actions may be appropriate.

If APHIS determines that an incident involving regulated GE plant material could pose a risk to plant health or the environment, APHIS will take appropriate remedial steps using its authority under the Plant Protection Act. In cases in which APHIS determines that remedial action is not necessary to mitigate LLP of regulated GE plant material to protect plant health and the environment, APHIS is not precluded from taking enforcement action against a company or individual for violations of APHIS regulations. For more information on the policy, and to view the

accompanying documents including the policy document and a factsheet, please visit <http://www.aphis.usda.gov/newsroom>.

Additionally, the issue of low-level presence is being addressed at the international level through a working group of the Codex Alimentarius' Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. During the week of March 13, representatives of 23 countries participated in a meeting of the working group, which was formed following a task force meeting in Japan last November. The group made extraordinary progress in developing an annex to the current Codex guideline for food safety assessments of foods derived from GE plants. The annex will cover the elements of a safety assessment for the low-level presence of GE material in food. In addition, the group worked to identify information-sharing mechanisms to facilitate utilization of the annex. The United States is pleased that its effort to raise awareness of this issue at an international level has resulted in action by the international community, and hopes that a draft annex will be adopted by Codex this Fall.

Update on Clearfield 131 Rice

On March 22, APHIS announced that testing conducted by two USDA laboratories – as part of an ongoing investigation into the presence of minute levels of regulated genetic material found in Clearfield 131 (CL131) rice seed – has identified LLRICE604 as the source of the genetic material. LLRICE604 was developed by Bayer CropScience for herbicide tolerance as part of the LLRICE600 series. The protein contained in LLRICE604, phosphinothricin-N-acetyltransferase, (PAT), has a long history of safe use and is present in many deregulated products.

FDA concluded that the presence of rice from the LLRICE 600 series at low levels in food and feed would pose no food or feed safety concerns. Based on this determination, APHIS will not prevent movement or processing of CL131 rice from previous years. APHIS is providing anyone who was issued an emergency action notification (EAN) on March 4-5, with specific instructions regarding appropriate seed disposition. Because LLRICE604 remains a regulated article, producers will not be permitted to plant any CL131 seed that is currently on hold.

BRS Issues New User's Guide Chapters

BRS is undertaking a major revision of its guidance on the regulation of GE organisms. The project will update and consolidate all agency guidance related to compliance with APHIS' biotechnology regulations (7 CFR 340) into a single printed publication, entitled the *BRS User's Guide*. In January 2007, the first two chapters of the new *BRS User's Guide* were posted online. These include a chapter on document preparation guidelines, including how to handle CBI, and guidance for notifications. As BRS completes new guidance chapters they will also be placed online, until all existing guidance is replaced with new guidance. All *BRS User's Guide* chapters are available at http://www.aphis.usda.gov/brs/brs_usersguide.html.

New Amendment Process Available in ePermits

As of January 4, 2007, applicants can apply on-line through ePermits for an amendment to a permit, as well as renew a permit. Applicants will be able to pull up existing permits in ePermits, and in the case of an amendment, make any desired additions or changes before submitting the newly amended permit. ePermits stores all versions of the permit starting with the original and all amendments, and keeps a record of renewed permits.

Update on GE Alfalfa and GE Creeping Bentgrass

BRS strives to ensure that all relevant environmental factors are considered and appropriate confinement measures are in place to protect plant health and the environment. Recently, APHIS was subject to two lawsuits involving GE alfalfa and GE creeping bentgrass that will affect the way BRS documents such considerations. A short summary of each of these important cases is provided below, with an update on how APHIS is responding to them.

GE Alfalfa

On June 14, 2005, APHIS deregulated GE Roundup Ready (RR) alfalfa after conducting an environmental assessment and a thorough review of scientific evidence. APHIS makes a determination of nonregulated status only when it can conclude that the organism poses no more of a plant pest risk than its conventional, non-GE, counterpart.

On March 23, APHIS published in the *Federal Register* a notice that the Agency will return to regulated status alfalfa lines J101 and J163 that are genetically engineered by the Monsanto Company and Forage Genetics International to be tolerant to the herbicide glyphosate. APHIS took this action in order to comply with a March 12, 2007, preliminary injunction order issued by a California U.S. District Court.

The court did not overturn federal conclusions regarding the safety of RR alfalfa for food and feed purposes, but rather concluded that APHIS had not adequately documented potential environmental impacts. A future decision regarding the deregulation of RR alfalfa will be issued only after the completion of an appropriately documented environmental analysis.

After the court issued its March 12, 2007, order, seed dealers were notified that seed can no longer be sold. Growers who had already purchased RR alfalfa seed as of March 12, could plant that seed before March 30, 2007. Growers who met these deadlines may harvest, use, and sell their RR alfalfa crop, as may growers who previously planted RR alfalfa. Any product grown from seed planted after this deadline will be subject to the full range of APHIS' remedial authorities.

GE Creeping Bentgrass

On February 5, 2007, the U.S. District Court of the District of Columbia issued its decision in a lawsuit filed by the International Center for Technology Assessment (ICTA) and the Center for Food Safety challenging APHIS' consideration of genetically engineered turf grasses.

The court ruled in favor of ICTA on two counts. The court found that APHIS did not give sufficient consideration to a petition requesting that glyphosate-tolerant creeping bentgrass be placed on the federal noxious weed list. The court vacated and remanded this count. The court also found that APHIS did not adequately comply with the National Environmental Policy Act (NEPA) requirements and APHIS implementation regulations. APHIS' NEPA-implementing regulations define which kinds of APHIS actions are "categorically excluded" from further NEPA analysis, and the court found that APHIS failed to adequately determine whether each field test fell within an exception to categorical exclusion. The court enjoined any further processing of permits or notifications unless this determination is made. On the third count, where ICTA claimed that USDA violated its own regulations when granting permission to carry out field tests for glyphosate-tolerant creeping bentgrass, the court ruled in favor of USDA.

APHIS' Response

APHIS complies with NEPA and since the lawsuits were initiated has instituted additional procedures and new documentation requirements to ensure that the Agency takes the appropriate steps and conducts an independent analysis to determine whether the field testing of a GE plant meets the criteria to qualify for a categorical exclusion from NEPA. In addition, APHIS implemented new guidance on permits and notifications to strengthen its NEPA and Endangered

Species Act process. All applicants should have received detailed instructions on these changes via email. For questions regarding submission of the required data, please contact Steven Bennett at Steven.m.bennett@aphis.usda.gov. For questions regarding critical habitat analysis, please contact Michael Blanchette at michael.p.blanchette@aphis.usda.gov.

BRS Employee Spotlight

In each quarterly stakeholder update, BRS will highlight one of our employees so that our stakeholders can see the variety of work done in our program.

Employee: Tom Sim

Position: Director, Regulatory Operations Program

Years with BRS: One—I joined BRS in November 2005.

Education: I have a B.S. degree in Botany and Plant Pathology from Oklahoma State University and a M.S. degree in Plant Pathology from Kansas State University. My Master's research focused on the inheritance of resistance in soybean of Phytophthora root rot disease.

Job Description: My primary job responsibility is to manage the Regulatory Operations Program in BRS. The program is comprised of two branches. The Document Management Branch deals with the receipt, processing, and issuance of permits and notifications as well as other management functions such as document control. The Compliance and Inspection Branch is responsible for managing site inspections, reviewing inspection reports, providing compliance assistance to industry, and assisting with investigations when needed. The BRS compliance effort is being strengthened to ensure the standards established by regulation are being met.

Proudest Accomplishment: Prior to joining BRS, I was the program manager of the Plant Protection and Weed Control program in the Kansas Department of Agriculture. One of this program's functions was to monitor the occurrence and distribution of plant pests in Kansas. This activity supported many plant pest regulatory activities including the export of Kansas agricultural commodities. In 1993, we organized a regional survey of wheat in Kansas, Nebraska, South Dakota, North Dakota, Oklahoma, and Texas for Karnal bunt, a wheat disease not known to exist in the United States. This survey generated negative data for Karnal bunt in 1993, 1994, and 1995 in the participating states. When this disease was discovered in the United States in Arizona in 1996, the data from this project was useful in maintaining wheat exports from the United States. Subsequently, the USDA patterned a national Karnal bunt survey in the United States after this successful regional project.

What motivates you about your job: The Regulatory Operations Program is the newest unit within BRS. I have the unique opportunity to build and shape this new program so that the compliance and permitting functions of BRS can provide the same high level of service and expertise as the other BRS units. I enjoy analyzing problems and finding efficient and effective solutions. Building good working relationships with external and internal customers is something that I strive for. I enjoy the challenges and opportunities that BRS has presented.

Administrative Update

Donna Malloy has been selected to be BRS' Animals Branch Chief, beginning on April 15. Donna holds a D.V.M. degree and a M.P.H. degree, in addition to a B.S. in Animal Science. She has served in several different programs within APHIS over 20 years. Donna worked on BRS'

transgenic animals task force and has experience in activities related to promoting and protecting animal and public health, protecting our borders from important diseases, and assessing the safety of a wide variety of veterinary biological products, including those derived using biotechnology.

In January, BRS gained two new Biotechnologists in the Environmental Risk Analysis Programs, Plants Branch—Natalia Weinsetel and Subray Hegde. Natalia was a summer intern with BRS in 2005 and 2006 as part of the USDA Public Service Leaders Scholarship Program. She has a Ph.D. in Food Science and Technology and B.S. and M.S. degrees in Biology. She has teaching assistant and laboratory experience in food science and processing, cellular and molecular biology, and biotechnology. Subray comes to BRS from the University of California, Riverside, where he was a Postgraduate Research Geneticist. He received his B.S., M.S. and Ph.D. in Plant Breeding and Genetics. He has developed several experimental hybrids in several crops and trees and has training in plant biotechnology, genetic engineering, and bioinformatics.

Interested in Working in BRS?

If you or someone you know is interested in working for BRS, you can view and apply for current job vacancies by visiting <http://jobsearch.usajobs.opm.gov/> and searching for “Biotechnology Regulatory Services” (in quotes).

Have questions about BRS policy and regulations? E-mail us at biotechquery@aphis.usda.gov

Year-to-Date Submissions through March 31, 2007

Notifications Acknowledged

101	Importation
95	Interstate Movement
143	Environmental Release
395	Combined Interstate Movement/Release

Permits Issued

27	Importation
23	Interstate Movement
14	Environmental Release
116	Courtesy Permits

0 Petitions/Extensions to Grant Non-Regulated Status Received